

K253486 SKIA-Head (Model: SKIA-ST00)Feb 23, 2026
129 days to decisionK253486 · Product code: **LLZ** · Radiology
Source: <https://www.510kdatabase.net/k253486/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Image Processing, Radiological (LLZ)
Date received	Oct 17, 2025
Decision date	Feb 23, 2026
Days to decision	129 days
Third-party review	Yes
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Skia, Inc.
Location	Seoul, KR
Contact	Jong Myoung Lee
510(k) history	1 submissions · 1 cleared · 2026-2026

REGULATORY CONSULTANT

Consulting firm	Third Party Review Group, LLC
Contact	Dave Yungvirt

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)

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